

K032127

510K Summary of Safety and Effectiveness

1. Sponsor Name
Hemedex, Inc.
222 Third Street, Suite T123
Cambridge, MA 02142
USA
2. Device Name
QFlow 500 Probe Fixation Disk
3. Identification of Predicate or Legally Marketed Device
UreSil Fixation Device (K914699)
4. Device Description
The Hemedex Fixation Device is a compact soft silicone disk with a securing clamp and adhesive dressing for securing a probe or catheter to the patients skin. The clear pressure sensitive adhesive dressing allows for easy visual inspection of catheter entry site.
5. Intended Use
The Hemedex Fixation Device is intended to be used on the patient's skin to secure the percutaneous placement of the QFlow Perfusion Probe
6. Comparison of Technological Characteristics
This device is the exact same device as that marketed by UreSil under K914699 except the diameter has been reduced to accommodate the QFlow Probe OD. The materials are the same as that in K914699. In fact UreSil is the manufacturer of the Hemedex Fixation device.
7. Performance Testing
Bench testing was conducted to demonstrate that this device meets the requirements of its intended use and meets the specified performance criteria.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Hemedex, Inc.
c/o Ms. Debbie Iampietro
President, QRC Consulting
7 Tiffany Trail
HOPKINTON MA 01748

DEC 30 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Re: K032127

Trade/Device Name: Hemedex Fixation Device
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Product Code: 78 KYN
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Product Code: 78 FGE
Regulation Number: 21 CFR §870.2100
Regulation Name: Cardiovascular blood flow meter
Regulatory Class: 74 DPW
Regulation Number: 21 CFR §870.2120
Regulation Name: Extravascular blood flow probe
Product Code: 74 DPT
Regulatory Class: II
Dated: October 2, 2003
Received: October 3, 2003

Dear Ms. Iampietro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

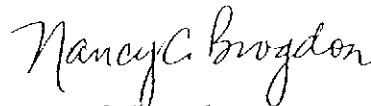
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

July 1, 2003

510(k) Number (if known): K032127

Device Name: Fixation Device

Indications For Use:

The Hemedex Fixation Device is intended to be used on the patient's skin to secure the percutaneous placement of the QFlow Perfusion Probe.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032127